

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

ASTRAZENECA AB, AKTIEBOLAGET
HÄSSLE, ASTRAZENECA LP, KBI INC.
and KBI-E INC.,

Plaintiffs,

v.

MYLAN LABORATORIES LIMITED and
MYLAN, INC.,

Defendants.

Civil Action No. 12-1378 (JAP) (TJB)

Motion Return Date: July 15, 2013

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**DEFENDANTS' BRIEF IN FURTHER SUPPORT OF PLAINTIFFS' MOTION TO
SEAL (ECF NO. 105) THEIR MOTION TO AMEND THE COMPLAINT AND
SUPPORTING DOCUMENTS THERETO (ECF NOS. 83, 88)**

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PRELIMINARY STATEMENT

Defendants/Counterclaim-Plaintiffs Mylan Laboratories Limited and Mylan Inc. (collectively, “Mylan”) submit this Brief in further support of Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc., and KBI-E Inc.’s (collectively, “AstraZeneca”) Motion, pursuant to Local Civil Rule 5.3(c), to Seal (ECF No. 105) the following documents (collectively referred to herein as the “Confidential Documents”) that AstraZeneca electronically filed in support of its Motion to Amend the Complaint to Assert Infringement of U.S. Patent No. 5,948,789 (ECF No. 83) and Reply in further support thereof (ECF No. 88):

- Portions of AstraZeneca’s Brief in Support of its Motion to Amend the Complaint to Assert Infringement of U.S. Patent No. 5,948,789 (ECF No. 83);
- Portions of the Declaration of Enrique D. Longton (ECF No. 83);
- The entirety of Exhibit A to the Declaration of Enrique D. Longton (ECF No. 83);
- Portions of Exhibit C to the Declaration of Enrique D. Longton (ECF No. 83);
- Portions of AstraZeneca’s Reply Brief in Support of its Motion to Amend the Complaint to Assert Infringement of U.S. Patent No. 5,948,789 (ECF No. 88); and
- The entirety of Exhibits A and B to the Declaration of Enrique D. Longton (ECF No. 88).¹

The Confidential Documents contain information that Mylan has designated as confidential, internal proprietary trade secret, business, and technical information under the Discovery Confidentiality Order entered by this Court on August 7, 2012 (ECF No. 39). These Confidential Documents in particular contain and/or reflect information contained in or derived from Mylan’s Abbreviated New Drug Application (“ANDA”), including the proprietary Drug Master File (“DMF”) referenced in its ANDA, other confidential submissions to the United

¹ The specific portions that Mylan seeks to seal are reflected in the proposed redacted versions that AstraZeneca electronically filed in support of its Motion to Seal (*see* ECF No. 105).

States Food and Drug Administration (“FDA”) for its products, and confidential manufacturing, formulation, and research and development information. This proprietary trade secret, business, and technical information is presently confidential and unavailable to the public. Disclosure of such confidential information could seriously impair and injure Mylan’s competitive posture in the marketplace. Mylan’s competitors could misappropriate Mylan’s highly confidential proprietary information to Mylan’s detriment in a highly competitive and time sensitive industry.

Accordingly, it is respectfully requested that the Court grant Plaintiffs’ Motion to Seal the Confidential Documents for the reasons set forth herein.

STATEMENT OF FACTS

Mylan respectfully incorporates herein the factual details set forth in the Proposed Findings of Fact and Conclusions of Law submitted herewith regarding the documents and information sought to be sealed herein. Those facts demonstrate the highly confidential and proprietary nature of the information that is the subject of this motion.

LEGAL ARGUMENT

I. The Applicable Legal Standards for a Motion to Seal

The Third Circuit recognizes a presumptive public right of access to judicial proceedings and records. In re Cendant Corp., 260 F.3d 183, 192 (3d Cir. 2001) (citing Littlejohn v. BIC Corp., 851 F.2d 673, 677-78 (3d Cir. 1988)). The public’s right of access is “not absolute” and must be balanced against the “litigant’s interest in secrecy.” Leucadia, Inc. v. Applied Extrusion Techs., Inc., 998 F.2d 157, 165 (3d Cir. 1993) (internal quotations and citations omitted). The party seeking to seal any part of a judicial record has the burden to show that disclosure would result in a “clearly defined and serious injury” that outweighs the public’s interest in the materials. Pansy v. Borough of Stroudsburg, 23 F. 3d 772, 786 (3d. Cir. 1984). To prevent

injury to a litigant's competitive standing in the marketplace, courts may protect "trade secrets or other confidential business information" from disclosure. Leucadia, 998 F.2d at 166 (internal citations omitted).

Local Civil Rule 5.3(c) places the burden of proof on the moving party as to why a motion to seal or otherwise restrict public access should be granted. Specifically, it requires a showing of:

- (a) the nature of the materials or proceedings at issue;
- (b) the legitimate private or public interest which warrants the relief sought;
- (c) the clearly defined and serious injury that would result if the relief sought is not granted; and
- (d) why a less restrictive alternative to the relief sought is not available.

The information contained in the Confidential Documents that is the subject of Plaintiffs' Motion to Seal relates to commercially sensitive and/or proprietary non-public trade secret and technical information. Specifically, the Confidential Documents contain and/or reflect information contained in or derived from Mylan's ANDA and other confidential submissions to FDA concerning its ANDA.

II. Under Local Civil Rule 5.3(c)(2)(b), Legitimate Interests Warrant the Sealing of the Confidential Documents

Courts have recognized that the public right of access to judicial proceedings and records is not absolute and may be rebutted. Republic of the Philippines v. Westinghouse Elec. Corp., 949 F.2d 653, 662 (3d Cir. 1991). "Every court has supervisory power over its own records and files, and access has been denied where court files might have become a vehicle for improper purposes." Littlejohn, 851 F.2d at 678 (quoting Nixon v. Warner Commc'ns, Inc., 435 U.S. 589, 598 (1978)). Courts may deny access to and seal a document when it encompasses business

information that might harm a litigant's competitive standing. See Littlejohn, 851 F.2d at 678 (citation omitted).

The District of New Jersey has held that the inclusion of trade secrets and other confidential information in documents warrant the sealing of such documents. "A well-settled exception to the right of access is the 'protection of a party's interest in confidential commercial information, such as a trade secret, where there is a sufficient threat of irreparable harm.'" In re Gabapentin Patent Litig., 312 F. Supp. 2d 653, 664 (D.N.J. 2004) (citation omitted). "The presence of trade secrets or other confidential information weighs against public access and, accordingly, documents containing such information may be protected from disclosure." Id. (citations omitted). As such, a party's confidential processes, chemical formulas and specifications, and research information should be sealed. Id. at 667-68; see Vista India, Inc. v. Raaga, LLC, 2008 WL 834399, at *2 (D.N.J. Mar. 27, 2008) (protecting "any formula, pattern, device, or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it") (ultimately quoting Restatement (Second) of Torts § 757 comment b).

Indeed, information included in an ANDA often consists of trade secrets or highly sensitive commercial information, and federal law requires that such information remain confidential. See Gabapentin, 312 F. Supp. 2d at 667 n.7 (citing 21 C.F.R. § 314.430(b)-(d)). As such, a party's confidential processes, chemical formulas and specifications, and research information should be sealed. Gabapentin, 312 F. Supp. 2d at 667-68.

The private interests at stake in this action warrant the relief sought. Here, Plaintiffs and Mylan – private parties – are in a dispute relating to patents and generic drug products. Sealing the identified documents as requested herein serves to protect the private proprietary business

interests of Mylan, which has a legitimate interest in ensuring that its confidential and proprietary non-public information remain undisclosed. If this information were to become publicly available, then Mylan's competitors could potentially (and likely would) use that information in the highly competitive pharmaceutical product marketplace. Therefore, the release of Mylan's confidential information poses a substantial risk of harm to Mylan's legitimate business interests and competitive position. Indeed, the federal government has recognized this interest by requiring that ANDAs remain confidential.

III. Under Local Civil Rule 5.3(c)(2)(c), Serious Injury Would Result If The Confidential Documents Were Not Sealed

This Court has discretion to balance the factors for and against access to court documents. See Pansy v. Borough of Stroudsburg, 23 F.3d 772, 781 (3d Cir. 1994). Protection of a party's interest in confidential commercial information, such as a trade secret, is a sufficient threat of irreparable harm, and is clearly defined as a serious injury. See Publicker, 733 F.2d at 1071.

If relief is not granted, highly sensitive and confidential trade secret, business, and technical information will be compromised, exposing Mylan to substantial financial risks. Unless the Confidential Documents are filed under seal, competitors and others will have access to important confidential and/or proprietary business information of Mylan that ordinarily would not be available to the public, let alone to its competitors in this highly competitive industry. Competitors and others in the marketplace might exploit such information to their advantage and benefit, and to Mylan's unfair detriment.

The competitive harm will be especially great in the present instance because the manufacture of pharmaceuticals is highly regulated by FDA and is subject to the statutory framework of the Hatch-Waxman Act. Filing and approval of ANDAs for generic companies

are time-sensitive and are directly tied to competitive advantages such as statutory market exclusivities and product launch dates. If a competitor gains access to confidential details involving manufacturing methods and materials choices, it could obtain the benefit of Mylan's substantial investments in research and development to its benefit without having to make its own expenditures of time and resources to do so. This head start that competitors may derive is a significant competitive harm that would result from the disclosure of the information and documents identified in this motion.

IV. Under Local Civil Rule 5.3(c)(2)(d), No Less Restrictive Alternative Is Available

Once confidential information is disclosed to the public, it can never again be sealed or maintained as private. This concern must be balanced with the requirement that only the "least restrictive alternative" be utilized to restrict public access to judicial proceedings. Publicker, 733 F.2d at 1073.

No less restrictive alternative to sealing is available because Mylan's request is tailored to seal only the specific confidential information contained in the documents identified above, the release of which would pose a financial and competitive risk to Mylan. Accordingly, the only way to protect the interests of Mylan is to seal the specific information contained in the Confidential Documents identified herein.

CONCLUSION

For the foregoing reasons, Mylan respectfully requests that the Court grant Plaintiffs' Motion to Seal the Confidential Documents.

Respectfully submitted,

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